

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance imidacloprid¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State Germany, for the pesticide active substance imidacloprid are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory mammalian toxicology and ecotoxicology data. The conclusions were reached on the basis of the evaluation of the representative uses of imidacloprid as an insecticide on apples, tomatoes and sugar beet. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. No concerns are identified.

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KEY WORDS

imidacloprid, peer review, risk assessment, pesticide, insecticide

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² Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011 and Commission Implementing Regulation (EU) No 485/2013. It was a specific provision of the approval that the applicant was required to submit to the European Commission by 31 July 2011 further studies to address the risk assessment for operators and workers, and the risk to birds and mammals.

In accordance with the specific provision, the applicant, Bayer CropScience, submitted an updated dossier in July 2011, which was evaluated by the designated RMS, Germany, in the form of an Addendum to the Draft Assessment Report. In compliance with the Guidance Document SANCO 5634/2009 rev.4.5, the RMS distributed the Addendum to Member States, the applicant and the EFSA for comments on 26 January 2012. The RMS collated all comments in the format of a Reporting Table, which was submitted to the European Commission in May 2012. As a follow up, the open points of the Reporting Table were evaluated by the RMS in revised addenda and a further commenting was launched on 18 December 2012. The comments were summarised by the RMS in a revised Reporting Table, which was submitted to the European Commission in May 2013.

Following consideration of the comments received, the European Commission requested the EFSA to deliver its conclusions on the RMS's evaluation of the confirmatory data submitted in relation to the risk assessment for operators and workers, and as regards the risk to birds and mammals.

EFSA concluded that the confirmatory data requirements on information to further address the risk assessment for operators and workers have been fulfilled.

It was concluded that the confirmatory data assessments for birds and mammals addressed the issues that had been identified as concerns. However some uncertainties were identified.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background	4
The active substance and the formulated product	6
Conclusions of the evaluation	6
1. Mammalian toxicity	6
2. Ecotoxicology	7
3. List of studies to be generated	9
4. Particular conditions proposed to be taken into account to manage the risk(s) identified.....	9
5. Concerns	9
5.1 Issues that could not be finalised	9
5.2 Critical areas of concern	9
6. Overview of the concerns identified for each representative use considered	10
References	11
Appendices	12
Abbreviations	18

BACKGROUND

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC³, and has been deemed to be approved under Regulation (EC) No 1107/2009⁴, in accordance with Commission Implementing Regulation (EU) No 540/2011⁵, as amended by Commission Implementing Regulation (EU) No 541/2011⁶ and Commission Implementing Regulation (EU) No 485/2013⁷. EFSA previously finalised a Conclusion on this active substance on 29 May 2008 in the EFSA Scientific Report (2008) 148 (EFSA, 2008). In addition, a specific Conclusion was issued on 19 December 2012 concerning the risk assessment for bees (EFSA, 2013).

It was a specific provision of the approval that the applicant was required to submit to the European Commission by 31 July 2011 further studies to address the risk assessment for operators and workers, and the risk to birds and mammals.

In accordance with the specific provision, the applicant, Bayer CropScience, submitted an updated dossier in July 2011, which was evaluated by the designated rapporteur Member State (RMS), Germany, in the form of an Addendum to the Draft Assessment Report (Addendum 7 dated January 2012; see Germany, 2014). In compliance with the Guidance Document SANCO 5634/2009 rev.4.5 (European Commission, 2011), the RMS distributed the Addendum to Member States, the applicant and the EFSA for comments on 26 January 2012. The RMS collated all comments in the format of a Reporting Table, which was submitted to the European Commission in May 2012. As a follow up, the open points of the Reporting Table were evaluated by the RMS in revised addenda (revised Addendum 7 dated May 2012 and Addendum 8 dated October 2012; see Germany, 2014) and a further commenting was launched on 18 December 2012. The comments were summarised by the RMS in a revised Reporting Table, which was submitted to the European Commission in May 2013.

Following consideration of the comments received, the European Commission requested the EFSA to deliver its conclusions on the RMS's evaluation of the confirmatory data submitted in relation to the risk assessment for operators and workers, and as regards the risk to birds and mammals.

The addenda and the Reporting Table were discussed at the Pesticides Peer Review Experts' Meeting 105 (ecotoxicology) and the Pesticides Peer Review Experts' Teleconference TC 96 (mammalian toxicology) on imidacloprid in September – October 2013. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting reports.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in March 2014.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to the risk assessment for operators and workers, and as regards the risk to birds and mammals. A key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and

³ Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include acetonitrile, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86-91.

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

⁷ Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p. 12-26.

address all issues raised in the peer review, from the compilation of comments in the Reporting Table to the conclusion. The Peer Review Report (EFSA, 2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the Reporting Table,
- the report of the scientific consultation with Member State experts,
- the comments received on the draft EFSA conclusion.

Given the importance of the confirmatory data addenda to the DAR in the format of a final addendum (compiled version of March 2014 containing all individually submitted addenda (Germany, 2014)) and the Peer Review Report, these documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Imidacloprid is the ISO common name for (*E*)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine (IUPAC).

The representative formulated products for the original evaluation were "Confidor", a soluble concentrate formulation (SL) and "Gaucho", a flowable concentrate for seed treatment (FS).

The evaluated representative uses in the original peer review were as an insecticide seed treatment for sugar beet and as a foliar spray for apples and tomatoes. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

The applicant has submitted to the Commission by the deadline of 31 July 2011 additional information as a response to the confirmatory data requirements on:

- information to further address the risk assessment for operators and workers;
- information to further address the risk to birds and mammals.

The assessment of the information was presented in confirmatory data addenda (Germany, 2014).

1. Mammalian toxicity

During the original peer review EFSA concluded that the representative uses of imidacloprid on tomato and apple will not result in an operator, worker and bystander exposure exceeding the acceptable operator exposure level (AOEL) of 0.08 mg/kg bw per day (EFSA, 2008). The applicant did not submit additional data concerning the representative uses on tomato and apple. In the framework of this conclusion a re-assessment of the dermal absorption values for the formulation 'Confidor SL 200', and the operator, worker and bystander exposure estimates to imidacloprid in the formulation 'Confidor SL 200' (i.e. uses on apple and tomato) was not considered necessary.

Considering the representative use as an insecticide seed treatment on sugar beet, the operator and worker exposure estimates for imidacloprid in 'Gaucho FS 600' were above the AOEL of 0.08 mg/kg bw per day, using 100 % as a dermal absorption input value (in the absence of experimental data) in the Seed-TROPEX Model (EFSA, 2008). Following the approval of the substance the applicant was required to submit confirmatory data to further address the risk assessment for operators and workers for imidacloprid relevant for the formulation 'Gaucho FS 600' (i.e. seed treatment use on sugar beet).

To fulfil the confirmatory data requirements the applicant submitted new dermal absorption studies with the formulation 'Gaucho FS 350', and operator exposure studies to refine the risk for operators and workers to imidacloprid in 'Gaucho FS 600'. The refinement proposed by the applicant did not take into account the criteria for the interpretation of the dermal absorption studies as reflected in the new guidance document on dermal absorption (EFSA PPR Panel, 2012), which was not available at the time of the approval publication of imidacloprid. The proposed refinement is not satisfactory according to the current state of knowledge, however the submitted dermal absorption studies can be considered acceptable as regards the request that the applicant had to fulfil.

The experts discussed the new dermal absorption and operator exposure studies during the Pesticides Peer Review Experts' Teleconference 96 (22 October 2013).

Considering dermal absorption, the experts agreed that the dermal absorption values for 'Gaucho FS 350' were applicable to the representative formulation 'Gaucho FS 600'. The experts agreed on the dermal absorption values of 2 % for the dilution and 0.2 % for the concentrate.

Considering operator and worker exposure, the experts proposed to use the Seed-TROPEX Model as a first-tier approach. The exposure of operators was below the AOEL of 0.08 mg/kg bw per day (69.1 % of the AOEL⁸) only, if adequate personal protective equipment (coverall, gloves) and respiratory protective equipment (during cleaning activities) are used. Worker exposure during direct hand contact with the treated seeds was below the AOEL (4.5 % of the AOEL), assuming that workers wear adequate work clothing and gloves. The experts agreed that the new operator exposure studies should not be used in a second tier approach, however no further refinement was considered necessary.

EFSA concluded that the confirmatory data on information to further address the risk assessment for operators and workers addressed the issues that had been identified as concerns.

2. Ecotoxicology

The addendum for the ecotoxicological section included updated risk assessments for birds and mammals using the EFSA guidance document on birds and mammals (EFSA, 2009), based on the assessments submitted by the applicant. No updated risk assessments were available considering the pertinent SANCO/4145/2000 guidance document (European Commission, 2002), which was in place at the time of approval of imidacloprid.

It is noted that only those scenarios were updated for the representative uses on apple and sugar beet, where high risk could not be excluded by the original peer review (in 2007 - 2008) and no updates were provided for the tomato uses (as no concerns were raised for these uses in the original peer review). Therefore, currently, the risk assessments for birds and mammals are based partly on the SANCO/4145/2000 guidance document and partly on the EFSA guidance document.

The updated risk assessments for **birds** were discussed at the Pesticides Peer Review Experts' Meeting 105 (10 - 13 September 2013). The toxicological endpoint used for the acute risk assessment was agreed by all the experts, but some concerns were raised for the endpoint used for the reproductive risk assessments. However, considering all the data and information that were available, the majority of the experts agreed on the endpoint as suggested by the RMS (NOAEL of 9.3 mg/kg bw per day).

The updated risk assessments for the representative use on apple indicated a low risk to birds (including insectivorous birds). It is noted that this representative use includes two applications, but in the risk assessments the two applications were considered separately (i.e. no multi-application factor was used). Although this approach resulted in some uncertainty (imidacloprid is known as persistent and mobile in plants), the approach was considered to be appropriate taking into account the large application interval between the spray applications and the available margin of safety.

A low risk was also identified for birds consuming pelleted sugar beet seeds. However, a low risk could not be indicated by the lower tier risk assessments for the scenarios for birds consuming sugar beet seedlings. Therefore, refined risk assessments, considering additional data, were made available for these scenarios. The refinement steps were discussed but could not be fully agreed by the experts at the meeting. Overall, the experts concluded that, considering all the available data and evaluations, a low risk to birds can be concluded also for these scenarios (birds consuming sugar beet seedlings), using a weight-of-evidence approach. After the meeting, further assessments were included in an addendum (revised Addendum 7; Germany, 2014) in order to support the weight-of-evidence approach. It is noted that EFSA could not agree with some of the aspects considered in these assessments, in particular with the approach for the estimation of the residues in insects.

⁸ The EFSA PPR Panel has recently concluded that the toxicological reference values for imidacloprid may not be protective enough and should be reduced to safeguard against developmental neurotoxicity (EFSA PPR Panel, 2013). As a result of its review, the EFSA PPR Panel proposed to lower the AOEL to 0.06 mg/kg bw per day. The exposure estimates would be then 92.16 % and 6 % of the AOEL of 0.06 mg/kg bw per day for operators and workers, respectively, assuming the same type of personal protective equipment.

As regards **mammals**, updated risk assessments were available for the representative use in sugar beet, using EFSA, 2009. The consumption of pelleted seeds by wild mammals was considered as unlikely, therefore the risk from this route of exposure was considered as low. A low risk was also identified by the risk assessments for the scenarios for mammals consuming sugar beet seedlings. These assessments addressed the data gap for granivorous mammals identified by the original peer review from 2007 - 2008.

Overall, it is concluded that, under the current state of scientific knowledge, the confirmatory data assessments for birds and mammals addressed the issues that had been identified as concerns.

3. List of studies to be generated

This is a list of data gaps identified during the focussed peer review process of confirmatory data. Data gaps identified in the previously finalised EFSA Conclusions on this active substance (EFSA, 2008 and EFSA, 2013) that were not part of the focussed peer review process of confirmatory data remain as unchanged.

- No data gaps have been identified.

4. Particular conditions proposed to be taken into account to manage the risk(s) identified

This is a list of particular conditions identified during the focussed peer review process of confirmatory data. Particular conditions proposed in the previously finalised EFSA Conclusions (EFSA, 2008 and EFSA, 2013) that were not part of the focussed peer review process of confirmatory data remain as unchanged.

- The exposure of operators was below the AOEL of 0.08 mg/kg bw per day (69.1 % of the AOEL) only, if adequate personal protective equipment (coverall, gloves) and respiratory protective equipment (during cleaning activities) are used (relevant for the seed treatment use on sugar beet, see section 2).
- Worker exposure during direct hand contact with treated seed was below the AOEL (4.5 % of the AOEL), assuming that workers wear adequate work clothing and gloves (relevant for the seed treatment use on sugar beet, see section 2).

5. Concerns

5.1 Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011⁹, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

None.

5.2 Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

No critical areas of concerns are identified.

6. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 4, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Apple	Sugar beet/fodder beet
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Comments/Remarks			

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Summary of the representative uses applied for in the original peer review (Imidacloprid)*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g a.s./hL min - max (l)	water L/ha min - max	g a.s./ha min - max (l)		
Apple	Northern and Southern Europe	Confidor	F	<i>sucking and biting insect pests</i>	SL	200	SPI	1.BBCH 10 2.BBCH 69/71 or latest 14 d prior to harvest	1 1	--	7	500 - 1500	1. 70 2. 105	14	
Tomato	Southern Europe	Confidor	F	<i>aphids, white flies, leaf beetle</i>	SL	200	SPI	BIF	2	14	5	1000	100	3	
Tomato	Southern Europe	Confidor	G	<i>aphids, white flies, leaf beetle</i>	SL	200	SPI	BIF	2	14	5	1500	150	3	
Sugar beet, fodder beet	Northern Europe	Gaucha	F	<i>soil-dwelling and early leaf-feeding and sucking insect pests</i>	FS	600	BEZ/PIL	seed	1	--	n.a.	n.a.	117	n.a.	Seed rate 1.3 U/ha 1 U = 100,000 pelleted seeds

n.a. not applicable (fixed with time of seeding); SPI = high volume spraying (foliar application); BEZ/PIL = seed treatment; BIF = at infestation

* It is noted that this GAP table does not take into account changes to the representative uses occurred as a consequence of risk management decisions / regulatory measures taken since the original approval of the substance.

<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialicarb-isopropyl).</p> <p>(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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Mammalian toxicology

Summary (Annex IIA, point 5.10)

AOEL*

Value	Study	Safety factor
0.08 mg/kg bw per day	Dog, 28- & 90-day supported by subchronic rat neurotoxicity study	100

*In the framework of this conclusion a re-assessment of the reference values including the AOEL was not performed.

Dermal absorption (Annex IIIA, point 7.3)

Representative formulation: Confidor SL 200*

0.3 % (concentrate, 200 g/L) and 8 % (diluted formulation 0.7 and 0.07 g/L), based on an *in vitro* study on human skin with 'Confidor OD 200'.

Representative formulation: 'Gaucho FS 600'

0.2 % for the concentrate (350 g/L), 0.4 % for intermediate dose (70 g/L) formulation and 2 % for low dose (0.5 g/L) formulation based on triple pack calculation with 'Gaucho FS 350'.

*In the framework of this conclusion a re-assessment of the dermal absorption values of imidacloprid in the formulation 'Confidor SL 200' was not performed.

Exposure scenarios (Annex IIIA, point 7.2)

Operators

Confidor SL 200*:
 German model, without PPE:
 high crop 14 %, field crop 6 % of AOEL
 UK POEM, without PPE:
 high crop 15 %, field crop 7 % of AOEL,
 Greenhouse, without PPE: 27 % of AOEL

Gaucho FS 600:
 SeedTropex
 With PPE^(a) and without RPE^(b): 251.6 % of the AOEL.
 With PPE^(a) and RPE^(b) (cleaning), worst case for seed pelleting: seed treatment: 69 % of AOEL.

Workers

Confidor SL 200*:
 high crop: 12.6 % of AOEL, field crop: 6.0 % of AOEL

Gaucho FS 600:
 SeedTropex, loading and sowing of treated seed: 4.5 % of AOEL^(c)

*In the framework of this conclusion a re-assessment for operators and workers for imidacloprid relevant for the formulation 'Confidor SL 200' (i.e. use on apple and tomato) was not performed.

(a) PPE: personal protective equipment (coverall, gloves). In the SeedTropex studies operators wore coveralls and gloves for all tasks except for bagging when only coveralls were worn; therefore the estimated actual dermal exposure values reflect this level of PPE.

(b) RPE: respiratory protective equipment

(c) Assuming that workers wear adequate work clothing and gloves. For loading and sowing treated seed, the model was compiled by data from workers using different PPE, some workers wore gloves, others not.

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds				
<i>Coturnix japonica</i> ¹	a.s.	Acute	LD ₅₀ : 31	
Geometric mean of LD ₅₀ values for 4 species (<i>Coturnix japonica</i> , <i>Colinus virginianus</i> , <i>Anas platyrhynchos</i> , <i>Perdix perdix</i>) ²	a.s.	Acute	LD ₅₀ : 66	
<i>Colinus virginianus</i>	Confidor SL200	Acute	LD ₅₀ : 2515 (prod.) LD ₅₀ : 503 (a.s.)	
<i>Colinus virginianus</i> (chicks)	a.s.	Short-term	NOEL: 29.4	NOEC: 156
<i>Colinus virginianus</i>	a.s.	Long-term	NOAEL: 9.3	NOEC: 126
Mammals				
Mouse ¹	a.s.	Acute	LD ₅₀ : 131	
Geometric mean of LD ₅₀ values for 2 species (mouse, rat) ²	a.s.	Acute	LD ₅₀ : 256	
Rat	a.s.	Long-term	NOAEL: 17	NOEAC: 250
Additional higher tier studies				
-/-				

¹ endpoint used in the calculations not altered by the submitted confirmatory data

² endpoint used only in the revised calculations based on the submitted confirmatory data – see addendum 7 (Germany, 2014)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Apples (altered by the submitted confirmatory data; revised assessment for birds according to the EFSA Guidance, 2009; applications considered at either a) BBCH 10-19 or b) BBCH ≥40)

Indicator species/Category	Time scale	ETE/DDD	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivorous bird	Acute	a) 3.3 b) 4.9	a) 20.0 b) 13.5	10
Small omnivorous bird	Acute	a) 0.4 b) 0.2	a) 165 b) 330	10
Small granivorous bird	Acute	a) 1.5 b) 0.9	a) 44.0 b) 73.3	10
Small insectivorous bird	Long-term	a) 0.7 b) 0.1	a) 13.8 b) 9.2	5

Indicator species/Category	Time scale	ETE/DDD	TER	Annex VI Trigger
Small omnivorous bird	Long-term	a) 1.0 b) 0.04	a) 119 b) 209	5
Small granivorous bird	Long-term	a) 0.4 b) 0.2	a) 24.8 b) 44.0	5
Tier 1 (Mammals)				
Small herbivore	Acute	14.91	8.8	10
Small herbivore	Long-term	4.93	3.4	5
Higher tier refinement (Mammals)				
Common vole (<i>Microtus arvalis</i>) FOCUS interception 50 %	Acute	7.6	17	10
Common vole (<i>Microtus arvalis</i>) (see above)	Long-term	0.43	39.3	5

Tomatoes (no updates were provided in the framework of the confirmatory data assessment)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivore	Acute	5.37	5.8	10
Small insectivore	Short-term	3.00	9.8	10
Small insectivore	Long-term	3.00	3.1	5
Higher tier refinement (Birds)				
Yellow wagtail (<i>Motacilla flava</i>) insectivorous diet: arthropod RUD for 50 % large/50 % small arthropods	Acute	2.9	10.6	10
Yellow wagtail (<i>Motacilla flava</i>) (see above)	Short-term	1.5	19.6	10
Yellow wagtail (<i>Motacilla flava</i>) (see above)	Long-term	1.5	6.2	5
Tier 1 (Mammals)				
Wood mouse (<i>Apodemus sylvaticus</i>), replacing medium herbivorous mammal	Acute	12.69	10.3	10
Wood mouse (<i>Apodemus sylvaticus</i>), replacing medium herbivorous mammal	Long-term	3.61	4.7*	5
Higher tier refinement (Mammals)				

*: the risk was considered as low by the meeting of PRAPeR 33 (October, 2007)

Sugar beet (altered by the submitted confirmatory data; revised assessment for birds and mammals according to the EFSA Guidance, 2009)

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Tier 1 (Birds)				
Bird ingesting large grit particles	Acute	6.118	10.8	10
Small omnivorous bird (consumption of seedlings)	Acute	7.8*	8.5	10
Bird ingesting large grit particles	Long-term	0.652	14.3	5
Small omnivorous bird (consumption of seedlings)	Long-term	1.79**	5.2	5
Tier 1 (Mammals)				
Small omnivorous mammal (consumption of seedlings)	Acute	3.72*	68.8	10
Small omnivorous mammal (consumption of seedlings)	Long-term	0.864**	19.7	5
Higher tier refinement (Mammals)				

*: the exposure estimation already includes refinement for residue level in the seedlings

**: exposure estimation already includes refinements for residue level and residue decline in the seedlings

Notes: Further refined acute risk assessments were available for birds, but these assessments were not fully agreed by the peer review (2013 - 2014). However, these refined calculations were considered in a risk assessment using a weight-of-evidence approach. In addition, the DT_{50} considered for describing the residue decline (for the long-term risk assessments) had some uncertainties.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
μg	microgram
μm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC ₅₀	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organization of the United Nations
fd	feed
FIR	Food intake rate

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FS	flowable concentrate
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IENTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K _{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K _{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MATC	maximum allowable toxicant concentration
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	Millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake

ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OD	oil dispersion
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in sediment
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r ²	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SL	soluble concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t _{1/2}	half-life (define method of estimation)
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organization
wk	week
yr	year